Submitter Information

MAY - 3 2012

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 ph: (330) 425-1313 fax: (330) 963-0749
Contact:	Douglas J. Thistlethwaite
Date:	November 4, 2011

Device Name

Classification Name:	Computed tomography x-ray system
Classification Number:	90-IYN, 892.1550
Trade/Proprietary Name:	guideShot Option, SCENARIA Whole-body X-ray CT System
Predicate Device(s):	guideShot Option, ECLOS Computed Tomography X-ray System (K091103)

Device Intended Use

The SCENARIA Whole-body X-ray CT System with guideShot Option is a x-ray imaging device that produce cross-sectional images of the body at different angles. The system reconstructs, processes, displays, and stores the collected images. The guideShot Option adds a remote in-room display and controls to support interventional imaging. The device output can provide an aid to diagnosis when used by a qualified physician.

Device Description

Function

The SCENARIA Whole-body X-ray CT System is a multi-slice computed tomography system that uses x-ray data to produce cross-sectional images of the body at various angles. The guideShot Option adds a remote monitor and controls at the patient table to allow the operator to initiate data collection and to view resulting CT images in order to support interventional procedures.

Scientific Concepts

The SCENARIA Whole-body X-ray CT System uses 64-slice CT technology, where the X-ray tube and detector assemblies are mounted on a frame that rotates continuously around the patient using slip ring technology. The solid-state detector assembly design collects up to 64 slices of data simultaneously. The X-ray sub-system features a high frequency generator, X-ray tube, and collimation system that produces a fan beam X-ray output. The system can operate in a helical (spiral) scan mode where the patient table moves during scanning. As the X-ray tube/detector assembly rotates around the patient, data is collected at multiple angles.

The collected data is then reconstructed into cross-sectional images by a high-speed reconstruction sub-system. The images are displayed on a Computer Workstation, stored, printed, and archived as required. The workstation is based on current PC technology using the Windows™ operating system.

Physical and Performance Characteristics

The SCENARIA Whole-body X-ray CT System consists of a gantry, operator's workstation, patient table, high-frequency x-ray generator, and accessories. The guideShot option adds a remote monitor and footswitch to control acquisitions and display images in the scan room. The system performance is similar to the predicate device.

Performance Comparison

Because the SCENARIA Whole-body X-ray CT System with guideShot Option and the predicate device are both Hitachi designs, they were subjected to the same non-clinical evaluations as stipulated in 21 CFR 1020.33(c). Evaluations include: dose profile, image noise, modulation transfer function (MTF), slice thickness and sensitivity profile, slice plane location, and CT dose index.

The evaluation results of the SCENARIA Whole-body X-ray CT System with guideShot Option were comparable to the predicate device and support our conclusion that the system is substantially equivalent.

Device Technological Characteristics

The SCENARIA Whole-body X-ray CT System with guideShot Option acquires data in the same manner as the predicate device. Physically, the SCENARIA Whole-body X-ray CT System with guideShot Option is very similar to the predicate device. The key differences are the ability to initiate a scan and display data in the scan room.

The ability to collect and display image on an in-room monitor does not change the essential characteristics of the finished images. The operation of the system is virtually identical to the predicate because guideShot simply adds remote display and controls to the predicate device. The SCENARIA Whole-body X-ray CT System operating system software is essentially the same, as well as the user interface. The patient table design and gantry controls are unchanged.

In conclusion, the SCENARIA Whole-body X-ray CT System with guideShot Option is technologically equivalent in concept, function, and performance to the predicate device.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. the SCENARIA Whole-body X-ray CT System with guideShot Option is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the ECLOS Computed Tomography X-ray System with guideShot Option (K091103).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

MAY - 3 2012

Re: K113341
Trade/Device Name: guideShot Option, SCENARIA Whole-body X-ray CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 13, 2012
Received: April 18, 2012

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: guideShot Option, SCENARIA Whole-body X-ray CT System

Indications For Use:

The SCENARIA Whole-body X-ray CT System with guideShot Option is a x-ray imaging device that produce cross-sectional images of the body at different angles. The system reconstructs, processes, displays, and stores the collected images. The guideShot Option adds a remote in-room display and controls to support interventional imaging. The device output can provide an aid to diagnosis when used by a qualified physician.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113341